


DECLARATION OF CONFORMITY / DECLARATION DE CONFORMITE
Validity declaration of conformity from date / Date de déclaration de conformité :

Place / Lieu d'émission :

bioMérieux SA
376 Chemin de l'Orme
69280 Marcy l'Etoile - FRANCE

Date of the issue of the declaration of conformity /
Date d'application de la déclaration de conformité :

25 July 2016

Name - Title / Nom - Fonction :

Nathan Hardesty, Manager, Regulatory
Affairs Microbiology

Signature :

Product identification / Identification du produit :

Name / Nom :

VITEK® MS & Accessories

VITEK® MS Instrument	Ref. 410895
VITEK® MS Instrument for Japan	Ref. 412550
VITEK® MS Acquisition Station	Ref. 413654
VITEK® MS Prep Station	Ref. 414053
VITEK® MS RP5700 Master DVD V2 Clinical	Ref. 413242
VITEK® MS RP5700 DVD Update to V2 Clinical	Ref. 413655
VITEK® MS RP5800 PREP PC CLI	Ref. 415267
VITEK® MS RP5800 Acq PC Kit Clinical	Ref. 415706
VITEK® MS RP5800 DVD MAST V2.2 Clinical	Ref. 415708
VITEK® MS VITEK MS DVD MASTERS V3.0 CL KIT	Ref. 420950
VITEK® MS VITEK MS RP5800 DVD MASTERS V3.0 CL KIT	Ref. 420986
MYLA® V3.0.0 master DVD clinic	Ref. 412824
MYLA® V2 to V3 update CD	Ref. 413140
MYLA® PATCH 3.1.0 CD	Ref. 414391
MYLA® PATCH 3.2.0 CD	Ref. 414518
MYLA® Master DVD v3.2 CLI DL380	Ref. 415358
MYLA® Master DVD v4.0 CLINICAL	Ref. 416546
MYLA® v4 CLINICAL DL380 Server	Ref. 418291
MYLA® v4.1 Master DVD	Ref. 417191
MYLA® v4.1 CLI DL380 Server	Ref. 419061
MYLA® v4.1 DL380 Base OS	Ref. 419062
MYLA® CLI v3.X to v4.1 DL380 Server	Ref. 419071
MYLA® CLI v3.X to v4.1 ML350 Server	Ref. 419072


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MYLA® CLI v4.0 to v4.1 DL380 Server	Ref. 419073
MYLA® Server HP Driver Update	Ref. 419542
VITEK® MS-DS Target Slides	Ref. 410893
VITEK® MS-CHCA	Ref. 411071
VITEK® MS-FA	Ref. 411072
VITEK® MS Mycobacterium/Nocardia Kit	Ref. 415659
VITEK® MS Mould Kit	Ref. 415680

Identification of the person who has the power of attorney to bind the manufacturer / Nom et qualité de la personne engageant la responsabilité du fabricant :

Name / Nom : **Manuela Kaul**
 Title / Fonction : **VP Regulatory Affairs**

Identification of the legal entity / Identification de l'entité légale :

Manufacturer / Fabricant :
 Name / Nom : **bioMérieux SA**
 Address / Adresse : **376 Chemin de l'Orme
 69280 Marcy l'Etoile - FRANCE**

« We, the manufacturer declare that the above mentioned products comply with the Directives and their relevant implementations into all national laws of the member states into which we place the products » / « Nous, fabricant, déclarons que les produits mentionnés ci-dessus satisfont aux Directives et leurs transpositions en droit national dans les Etats Membres dans lesquels les produits sont mis sur le marché. »

Conformity assessment procedure used to demonstrate compliance / Procédure d'évaluation de conformité choisie :

Annex / Annexe (s) : **III (Section 6 excluded / exclue)**
 Directive (s) : **98/79/EC of the European parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices**

Device classification / Classification du dispositif :

Directive 98/79/CE : List(e) A, Annex(e) II List(e) B, Annex(e) II Other / Autre Self-testing / Autotest

Identification of certificate(s) and Notified Body which issued it (them) / Identification du (des) certificat(s) et Organisme Notifié :

Name of Notified Body / Nom de l'Organisme notifié : **N/A**



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Certificate(s) number / *Numéro d'identification* **N/A**
du(des) certificat(s) :

Prepared from the template Doc number 003535 Declaration of Conformity – en – fr – Editable - Revision 02.D

ATITIKTIES DEKLARACIJA

Vertimas iš anglų kalbos

**Atitikties deklaracijos galiojimas nuo datos**

Vieta:

bioMérieux SA
376 Chemin de l'Orme,
69280 Marcy l'Etoile - PRANCŪZIJA

Atitikties deklaracijos data:

2016 m. liepos 26 d.

Vardas – pareigos:

Nathan Hardesty, Direktorius,
Reglamentavimo reikalų skyrius,
Mikrobiologija

Parašas:

/parašas/

Produkto identifikacija

Pavadinimas:

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Asmens, kuris turi įgaliojimus nurodyti gamintoją šioje deklaracijoje

Vardas: **Manuela Kaul**
Pareigos: **VP Reglamentavimo reikalai**

Juridinio asmens identifikavimas

Gamintojas
Pavadinimas: **BIOMERIEUX SA**
Adresas: **376 Chemin de l'Orme,
69280 Marcy l'Etoile - PRANCŪZIJA**

<< Šiuo raštu mes, kaip gamintojas, tvirtiname, kad aukščiau minėti produktai atitinka Direktyvas ir atitinkamus jos perkėlimus į nacionalinius Sąjungos Šalių, į kurių rinką tiekiami produktai, įstatymus. >>

Atitikties atestavimo procedūra, nurodanti atitiktį

Priedas: **III (skyrius 6 neįtrauktas)**
Direktyva: **Europos Parlamento ir 1998 m. spalio 27 d. Tarybos direktyva 98/79/CE dėl in vitro medicinos priemonių.**

Prietaiso klasifikacija

Direktyva 98/79/CE: A Sąrašas, II Priedas B Sąrašas, II Priedas Kita
 Savaiminė patikra

Sertifikato ir jį (juos) išdavusios notifikuotosios įstaigos identifikacija:

Notifikuotosios įstaigos pavadinimas: **nėra duomenų**
Sertifikato numeris: **nėra duomenų**

Tikslus dokumento vertimas į lietuvių kalbą
Vertėjas (-a) *A. Gecelevičienė*
Data: *2016-10-05*
UAB Diamedica
Molėtų pl. 73, Vilnius
Lietuva
Tel: 8 5 279 0080